

In the Claims

Please amend the claims as follows:

Claims 1-9 (Canceled)

10. (Currently Amended) A process for [the] preparing [the] crystallised agglomerates comprising a clavulanate, with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded [of claim 1], which comprises stirring [at least one β -lactam] a clavulanate in a liquid phase.

11. (Previously amended) A process according to claim 10, wherein the liquid phase comprises a solvent or in a mixture of solvents together with one or more anti-solvents.

β^1 12. (Previously amended) A process according to claim 11, wherein the ratio of the weight of the solvent containing β -lactam to the anti-solvent is about 0.05 to 10 wt.%.

13. (Previously amended) A process according to claim 11, wherein the solvent is selected from the group consisting of water, alcohol, ketone and ester or a mixture thereof, wherein water is present in said mixture.

14. (Previously amended) A process according to claim 10, wherein the anti-solvent is a ketone, an ester, or an alcohol, or a mixture of these anti-solvents, optionally containing water.

Claim 15 (Canceled)

16. (Previously amended) A process according to claim 10, wherein the stirring is performed by applying stirring devices in one or more vessels, in-line mixers or a combination thereof.

17. (Previously amended) A process according to claim 16, wherein the stirring device is a high shear mixer.

18. (Currently Amended) A process according to claim [25] 10, wherein said stirring is performed by combining and permuting different stirring devices, the speeds of said devices, the type and amount of the solvents used, and mixing one or more solvents and anti-solvents.

19. (Currently Amended) A process according to claim 18, wherein the agglomerates have [various] an average particle size[s] between about 1 μm and 1500 μm .

β 1
20. (Previously Amended) A process according to claim 11, wherein the process comprises dissolving one or more β -lactams in a solvent, adjusting the pH to about neutral and mixing with the anti-solvent.

Claims 21-24 (Canceled)

25. (Previously added) A process according to claim 16, wherein the liquid phase comprises a solvent or in a mixture of solvents together with one or more anti-solvents.

Claim 26 (Canceled)

Please add the following claims:

27. (New) A process according to claim 19, wherein the agglomerates have an average particle size about 100 μm .

28. (New) A process according to claim 19, wherein the agglomerates have an average particle size about 1000 μm .

29. (New) A process according to claim 10, wherein the agglomerates have a bulk density between about 0.20 g/mL and 0.60 g/mL.

30. (New) A process according to claim 10, wherein the agglomerates have improved flowability relative to clavulanate needles.

31. (New) A process according to claim 10, wherein the agglomerates have compressibility between about 10 % and 40 %.
32. (New) A process according to claim 10, wherein said clavulanate comprises a clavulanate salt.
33. (New) A process according to claim 32, wherein said clavulanate comprises potassium clavulanate.
34. (New) A process according to claim 33, wherein the agglomerates further comprise amoxicillin.
35. (New) A process according to claim 10, wherein the agglomerates optionally contain one or more excipients.
36. (New) A process according to claim 35, wherein the one or more excipients are selected from the group consisting of microcrystalline cellulose and silica.
37. (New) An agglomerate of clavulanates, wherein said agglomerate has a bulk density of between about 0.2 g/mL and 0.6 g/mL, with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded.
38. (New) The agglomerate of claim 37, wherein said agglomerate has a compressibility of between about 10 and 40 %.
39. (New) The agglomerate of claim 37, further comprising amoxillin.
40. (New) The agglomerate of claim 37, further comprising one or more excipients.
41. (New) The agglomerate of claim 40, wherein said one or more excipients is selected from the group consisting of microcrystalline cellulose and silica.

42. (New) The agglomerate of claim 37, wherein said agglomerate has an average particle size between about 1 μm and 1500 μm .

43. (New) The agglomerate of claim 42, wherein said agglomerates has an average particle size of about 100 μm .

44. (New) The agglomerate of claim 42, wherein said agglomerate has an average particle size of about 1000 μm .

131 45. (New) The agglomerate of claim 37, wherein said agglomerate has improved flowability relative to clavulanate needles.

46. (New) The agglomerate of claim 37, wherein said clavulanates comprise potassium clavulanate.

47. (New) A pharmaceutical formulation comprising the agglomerate of claim 37 and one or more pharmaceutically acceptable excipients.

48. (New) The pharmaceutical formulation of claim 47, further comprising amoxicillin.

49. (New) The pharmaceutical formulation of claim 47, wherein said one or more pharmaceutically acceptable inert excipients is selected from the group consisting of microcrystalline cellulose and silica.

50. (New) A pharmaceutical dosage form comprising a pharmaceutical formulation of claim 47.
